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REMARKSSummary of Office Action

Claims 1-6 and 8-11 have been rejected under 35 U.S.C. § 103(a) as being obvious in view of Dakov U.S. patent 6,030,392 (hereinafter "Dakov").

Claims 1-11 have been rejected under 35 U.S.C. § 103(a) as being obvious over Dakov in view of van der Gaast U.S. patent 3,577,979 (hereinafter "van der Gaast").

Claims 1-6 and 8-11 have been rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Kornberg et al. U.S. patent 5,353,804 (hereinafter "Kornberg").

Claim 7 has been rejected under 35 U.S.C. § 103(a) as being obvious over Kornberg in view of van der Gaast.

Summary of Applicant's Reply

Claim 1 has been amended to more particularly define the invention. No new matter has been added, and the amendments are fully supported by the originally filed specification.

The Examiner's objections and rejections are respectfully traversed.

Statement Under 37 C.F.R. § 1.116(b)

Applicants respectfully request that the amendments presented herein be entered under 37 C.F.R. § 1.116(b)(3). Applicants believe that the proposed amendments place this application in condition for allowance. These amendments were not presented earlier because applicants believed that their previous reply was a good faith effort to advance the

prosecution of this application and that the amendments and arguments presented at that time were sufficient to place the application in condition for allowance. Applicants believe that that constitutes "good and sufficient cause why the [present] amendment is necessary and was not earlier presented."

Remarks on the § 103(a) Rejections Over Dakov

Claims 1-6 and 8-11 have been rejected under 35 U.S.C. § 103(a) as being obvious in view of Dakov.

Applicants' amended claim 1 describes an apparatus for cutting an aperture in a side wall of a patient's blood vessel. The apparatus includes a curvable delivery sheath configured to move axially along the interior of the blood vessel such that the distal end is proximate to an access site on the side wall. See, e.g., FIGS. 1-8.

Applicants' amended claim 1 also describes a curvable tissue-piercing structure configured to pierce the side wall by passing axially along the interior of the delivery sheath through the side wall substantially parallel to the longitudinal axis of the tissue-piercing structure and a hollow curvable annular tissue-cutting catheter disposed annularly around the tissue-piercing structure. The tissue-cutting catheter is configured for movement substantially parallel to the longitudinal axis of the tissue-piercing structure, and for rotation about the longitudinal axis to produce an annular cut through the side wall. Since the tissue-piercing structure is curvable, and the tissue-cutting catheter passes over the tissue-piercing structure, the tissue-cutting catheter is curvable as well. See FIGS. 1-8, specification at p. 6, 11.

12-19 ("The distal end of centering wire 30 is preferably deformable to facilitate deployment and removal...Centering wire 30 is kept relatively straight when it is inside sheath 20. But, when centering wire 30 is pushed axially out the distal end of sheath 20, it curves to one side..."), specification at p. 7, ll. 14-18 ("cutting catheter 40 is passed substantially coaxially over the centering wire and axially along the interior of sheath 20").

Dakov generally describes an annular rigid connector for hollow anatomical structures. In its specification, Dakov also generally describes a cutting instrument that creates a side opening in a hollow tubular organ. The cutting instrument is generally operated by using a barbed end 408 to pierce the outside wall of a hollow organ. The cutting cylinder 410 is then slid down the basic rod 402, cutting out the side wall of the hollow organ. The cutting instrument is then withdrawn, removing the cutout portion, which is mounted on the pointed barbed end 408. Dakov, col. 13, line 63 to col. 14, line 13 and figures 30-33.

Applicants respectfully submit that Dakov does not show or suggest an apparatus for cutting an aperture in a side wall of a patient's blood vessel comprising a curvable delivery sheath. No delivery sheath is mentioned in Dakov for use in conjunction with the cutting instrument described therein. Therefore, Dakov cannot show or suggest all of the limitations of applicants' claim 1.

Applicants also respectfully submit that Dakov does not show or suggest a curvable tissue-piercing structure, nor does it show or suggest a curvable tissue-cutting catheter. Instead, Dakov describes basic rod 402, which is rigid and

unflexible, unlike the tissue-piercing structure described in applicants' claim 1. Because cutting cylinder 410 slides over rod 402, it is not curvable, and therefore lacks the features of the tissue-cutting catheter described in applicants' claim 1. Therefore, Dakov cannot show or suggest all of the limitations of applicants' claim 1.

Accordingly, applicants respectfully submit that claim 1 and all claims that depend, directly or indirectly, therefrom are allowable over Dakov.

Remarks on the § 103(a) Rejections Over Dakov in view of van der Gaast

Claims 1-11 have been rejected under 35 U.S.C. § 103(a) as being obvious over Dakov in view of van der Gaast.

As discussed above with respect to the Section 103 rejections in view of Dakov, the cited references do not show or suggest an apparatus for cutting an aperture in a side wall of a patient's blood vessel comprising a curvable delivery sheath. Furthermore, the cited references do not show or suggest an apparatus comprising a curvable tissue-piercing structure or a curvable tissue-cutting catheter.

Accordingly, applicants respectfully submit that claim 1 and all claims that depend, directly or indirectly, therefrom are allowable over the combination of Dakov and van der Gaast.

Remarks on the Rejections Over Kornberg

Claims 1-6 and 8-11 have been rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Kornberg

In its specification, Kornberg generally describes an apparatus for percutaneous excisional breast biopsy, which includes a penetrating member in the form of a stylet with a tapered front end that can be guided along a localization guide wire. The apparatus uses a localizing needle to penetrate the breast, and the guide wire is slid through the localizing needle. Upon exiting the tip of the localizing needle, the guide wire expands and anchors itself in the surrounding breast tissue. A cannula is then used to cut out a biopsy specimen, which is removed. Kornberg, col. 7, line 37 to col. 8, line 30 and figures 2-6.

Applicants respectfully submit that Kornberg does not show or suggest an apparatus for cutting an aperture in a side wall of a patient's blood vessel comprising a curvable delivery sheath. No delivery sheath is mentioned in Kornberg for use in conjunction with the cutting instrument described therein. Even if Kornberg describes a structure analogous to a curvable delivery sheath, Kornberg does not describe a curvable delivery sheath configured to move axially along the interior of a blood vessel. Therefore, Kornberg cannot show or suggest all of the limitations of applicants' claim 1.

Applicants also respectfully submit that Kornberg does not show or suggest a curvable tissue-cutting catheter. Instead, Kornberg describes cannula 2, which must be rigid and inflexible, unlike the tissue-piercing structure described in applicants' claim 1, because sharp cutting device 5 is advanced through breast tissue 28 without external support. See Kornberg at col. 8, ll. 23-30. Therefore, Kornberg cannot show or suggest all of the limitations of applicants' claim 1.

Accordingly, applicants respectfully submit that claim 1 and all claims that depend, directly or indirectly, therefrom are allowable over Kornberg.

Remarks on the § 103(a) Rejection Over Kornberg in view of van der Gaast

Claim 7 has been rejected under 35 U.S.C. § 103(a) as being obvious over Kornberg in view of van der Gaast.

As discussed above with respect to the rejections in view of Kornberg, the cited references do not show or suggest an apparatus for cutting an aperture in a side wall of a patient's blood vessel comprising a curvable delivery sheath. Furthermore, the cited references do not show or suggest an apparatus comprising a curvable tissue-cutting catheter.

Accordingly, applicants respectfully submit that claim 7 is allowable over the combination of Kornberg and van der Gaast.

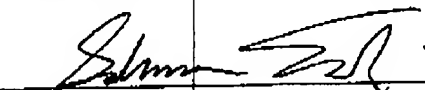
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Conclusion

In view of the amendments and remarks provided above, applicants respectfully submit that this application is in condition for allowance. Reconsideration and prompt allowance are respectfully requested.

Respectfully submitted,



Sahmon Torabi
Registration No. 59,281
Attorney for Applicants

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
Customer No. 1473
1211 Avenue of the Americas
New York, New York 10036-8704
Tel.: (212) 596-9000 (NY)
Tel.: (650) 617-4732 (CA)

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